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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**Washington, D.C. 20460**

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

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Subject: Your Letter of June 7, 2018 Responding to EPA's May 25, 2018 Letter Regarding the OxO  
American Chestnut and FIFRA

Thank you for your letter of June 7, 2018 and for the discussion on June 27, 2018 where you advocated that the OxO American chestnut should not be regulated as a pesticide. Subsequent to your letter and our discussion, we have further considered your position.

You concluded in your January 30, 2018 issue paper that "[t]he TG American chestnut is not a pesticide because there is no express or implied intent to mitigate any animate pest, only to minimize physical damage by neutralizing acid. The technology is not directed at the fungus and is indifferent to the continuing presence or absence of the fungus on the tree. The TG tree is intended to coexist with the fungus and the fungus will continue to grow and reproduce on the TG tree." In your June 7, 2018 letter, you further stated: "... we do not understand how your finding that the OxO reduces the physical effects on the tree arising from the presence of the fungus ... leads to the conclusion that the OxO American chestnut should be regulated as a pesticide."

After further consideration, we have confirmed our earlier determination communicated in our letter of May 25, 2018 that the OxO American chestnut contains a plant-incorporated protectant that meets the statutory definition of a "pesticide" under section 2(u) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 USC § 136(u). The term "mitigate" is generally defined to mean "make less severe or painful," and some of the synonyms for "mitigate," all meaning "to make something less grievous," include the following: "relieve, alleviate, lighten, assuage, ... and allay." See [ [HYPERLINK "https://www.merriam-webster.com/dictionary/mitigate"](https://www.merriam-webster.com/dictionary/mitigate) ]. We have determined that the meaning of "mitigate" in FIFRA applies to the OxO American chestnut since the net effect of the enzyme's action is to mitigate or lessen the effect of the Chestnut Blight fungal pathogen and thereby reduce the impact of a pest.

Please let us know if we can help you through the process should you proceed with an application for a FIFRA Section 3 registration for the OxO transgenic blight resistant chestnut. If you would like to discuss this further, please contact Mike Mendelsohn, Chief of the Emerging Technologies Branch at [ [HYPERLINK "mailto:Mendelsohn.Mike@epa.gov"](mailto:Mendelsohn.Mike@epa.gov) ].

Sincerely,

Robert McNally, Director  
Biopesticides and Pollution Prevention Division (7511P)  
Office of Pesticide Programs